

Clinical Laboratory Technology Advisory Committee
Minutes of the Meeting held on December 4, 2015
Meeting held by videoconference from CDPH Richmond campus,
KP Regional Laboratory, North Hollywood, and
Telephone Bridge Line

CLTAC members participating

John Bautista, Rhonda Becker, Richard Bennett, Marjorie Braasch, Patty Dadone, Lorri Dean-Yoakum, Elizabeth Dequinia, Kathleen Doty, Dan Leighton, Lee Hilborne, Rebecca Rosser, Fred Ung,

Former CLTAC members participating

Imre Fisher, Robert Footlik, Carmen Maldonado

CDPH staff participating

Karen Demby, Elsa Eleco, Elaine Flores, Ronald Harkey, Robert Hunter, Bridget Jones, Paul Kimsey, Tina Kruthoff, Tammy Pahlund, Robert Thomas, Victoria Maxwell, Donna McCallum, Jan Otey, Don Miyamoto, Desiri Moret-Blyden, Nai Saechao, Kathy Williams, Ellen Yasumura

Public members participating

Kathy Davis, Irene Dickman, Debbie Ferguson, Dora Goto, Brad Holmquist, Carolyn Howe, Curtis, Johnson, Julie Kingery, Shiu-Land Kwong, Lois Lang, Jill MacAfee, Jamie Marks, Karen Nickel, Rodney Roath, Barbara Sabella, Shannon Smith-Crowley, Phyllis Walker, Debbie Wilson-Ferguson, Tammy Zinsmeister

Welcome and general announcements

The meeting was called to order by CLTAC Chairperson Rhonda Becker at 9:03 a.m. Ms. Becker thanked Kaiser Permanente for sponsoring the videoconference center in North Hollywood and the telephone bridge.

Ms. Becker conducted a roll call of CLTAC members and other participants, and noted that a quorum of CLTAC members was present for the meeting.

Approval of minutes

Lee Hilborne moved to approve the minutes from the September 2015 meeting, Elizabeth Dequinia seconded the motion and the September minutes were approved by unanimous vote.

Department update

Dr. Paul Kimsey, Director of the Office of the State Public Health Laboratory Director (OSPHLD), reported that the California State Auditor (CSA) released an audit of Laboratory Field Services (LFS) that was discussed during the last CLTAC meeting. Since then, the Department has submitted a 60-day response that has been made available. The next deadline is the Corrective Action Plan (CAP) due at the end of December, which is in process within the Department. Robert Thomas, Acting Branch Chief of LFS, will set up subcommittees with the CLTAC; one of those would be

involved with the Department for response to the audit. There are deadlines but the Department wishes to have input from the CLTAC.

He noted that it was nearing the time for CLTAC members to submit the Form 700 to notify the Department of any conflict of interest they may have.

He reported that of the six State public health laboratories on campus, the two infectious disease laboratories and the infant botulism program have been reorganized and are being brought in under a new infectious disease branch. He noted that the position of branch chief was in the process of being filled and that he was asked to fill the post of interim chief in the meantime.

Legal update

Tammy Pahland, house counsel for LFS, reported that LFS met with the Medical Board of California (MBC) regarding a joint effort on the enforcement of Business and Professions Code (BCP) §650. She noted that both entities' approach at that point was educational. She reported that both entities would look to share information and communications, and LFS was looking to expand the effort to include seven boards in addition to the MBC professions. She reported that a follow-up meeting would occur in the coming month.

Robert Thomas noted that BCP §650 referred to inducements.

Ms. Pahland explained that there was a federal case where laboratories were providing free urine cups to offices and that was considered on a federal level to be an inducement. An inducement is usually not a monetary benefit between a laboratory and a medical professional, but there are financial gains. So if a physician office receives any consideration, value for service, or product it can be considered an inducement if it is not laid out.

Mr. Thomas mentioned that the memo on inducements gives examples and is posted on the LFS website.

Tammy Pahland reported on regulations, focusing on the more imminent ones. She reported that the repeal of California Code of Regulations (CCR) §1050 is being pursued as a Section 100 change that will allow the Department to skip a few steps in the regulatory process. It is justified by laws being in place that makes CCR §1050 ineffective, so it does not matter if CCR §1050 is on the books or not. The package is still on track to post in March 2016.

Tammy Pahland reported that an updated tracking log will be provided for the next meeting, but that two packages the sperm washing package, and the CLIA 2003 crosswalk part I, the automatic adoption of the CLIA standards that are as stringent or more stringent, will be taken off the tracking log. They will be tracked separately, as they are considered an Administrative Procedures Act (APA) exemption not requiring a full regulations package.

Bridget Jones reported that the personnel package is quite long at about 300 pages, but that the workgroup consisting of herself, Robert Thomas-Acting LFS Chief, Mary

Wogec-Associate Government Program Analyst, and Martha Obeso-Examiner II in the LFS Personnel Licensing Section are making progress. She reported that their goal is to have an initial draft by June 30, 2016.

She also reported that the information is conducive to charts that will make the regulations clearer and easier to understand, which met with general agreement. Karen Nickel asked whether CCR §1050 will be totally repealed or will it retain those areas that are more strict than CLIA as there are important items that she felt should be retained.

Ms. Pahland reported that Attorney, Evan Sznol is working on the repeal and they had run into a snag on a full repeal, but it was undergoing review in the regulation process team concurrent stage where each of the team members (regulations, legal, the assigned regulations attorney, house counsel, and program) were reviewing the final draft. She noted that it may return to a regular repeal.

Mr. Thomas noted that in the regulations tracking log distributed at the last meeting, the repeal of CCR §1050 was originally set to be handled in two parts, but that things are fluid and it was difficult to be specific about what parts would or would not be retained.

Ms. Pahland reported that SB 75, which passed in June, affected current California law and adopted in total Subpart K which had some items that are different from current California law.

Mr. Thomas added that Subpart K covered quality systems, which used to be called quality control (which includes pre-analytic, analytic, and post-analytic phases) so it is much broader, and the Crosswalk should be reduced in size because of SB 75.

LFS update

Mr. Thomas reported that while the Department could not always follow all of the CLTAC's recommendations, those recommendations carry great weight, and the Department appreciated the CLTAC's advice and active participation.

He reported that the section statistics included in the handouts had changed, and this report is the first presentation of a new, more standardized format. The Department's goal is to make data more meaningful. He noted that going forward, data will be provided in the same format so comparisons can be made and trends identified.

He reported that Mary Wogec has been working with the section chiefs and program staff to improve the LFS webpages and he invited everyone to visit the site. He reported that new information is often flagged and many pages have been added. He noted that some pages may come down briefly while being updated, so if a page disappears or stops functioning, visitors should try a little later.

He reported that there has been a noticeable increase in the number of Public Record Act (PRA) requests. He noted that not all requests are valid, which could lead to delays and frustration on the part of the requestor. He reported that general information on how to make a request can be found at the California Department of Public Health's (CDPH) website at www.cdph.ca.gov/Pages/PublicRecords.aspx, and requests could be made

through CDPH.INTERNETADMIN@cdph.ca.gov or directly to LFS through his office assistant, Nai Saechao (Nai.Saechao@cdph.ca.gov), who has been designated to handle and track PRAs to meet established response times.

He added that LFS does not accept subpoenas at their Richmond or Los Angeles offices. Subpoenas must be served in person at:

California Department of Public Health, Office of Legal Services
Laboratory Field Services
1415 L Street, Suite 500
Sacramento, CA 95814

He reported that adhering to the guidelines would reduce turnaround times.

He reported that LFS receives questions asking for clarity on wide range of issues. Staff who attempt to provide responses often find that the inquirer has posed the same question to other staff, section chiefs, or the branch chief. In addition, LFS is often asked to participate in and give presentations at membership organization meetings during which questions are asked and responses given that have been taken to be official interpretation of regulations. This has caused confusion as wide ranging changes have been made by constituents due to a response given to a small group.

He reported that LFS has been reminded that technically it is a regulatory body and cannot interpret law, which is a function of the courts. As a regulatory body, LFS can promulgate and enforce law, but while its opinion is obviously persuasive, it is not law and is not binding.

He reported that in an effort to improve transparency, LFS will try to provide a mechanism to address questions of law that will allow the regulated community to pose questions, which LFS will review and determine if they will address publicly based on the following factors:

- Affects large audience—i.e., questions of interpretation that affect a large number of stakeholders where additional clarity from LFS would assist both the regulated community and LFS staff.
- Public safety concerns—areas that pose a greater risk to public safety will be prioritized.
- Emerging fields or fields absent in CLIA—e.g., specimen sample source, molecular genetics as a specialty.

He noted that in the past, the CLTAC has been very helpful with giving position papers that have been posted on the LFS website and the Department would like to continue that practice by having the CLTAC vet selected questions. [He reported that

“LFS is requesting a motion to create an ongoing subcommittee to assist with LFS regulation packages. This subcommittee will serve as the conduit between the industry and interested stakeholders and LFS in order to provide feedback to LFS on its regulation packages. This may include answering directed questions and review of draft language. The purpose of this mechanism is to better address

consistency and clarity in LFS's regulations as well as identify possible regulatory needs.”]

He requested a motion to create an ongoing subcommittee to assist with LFS regulation packages by serving as a conduit between interested stakeholders and providing LFS with feedback on regulations packages to address issues of consistency and clarity and identify regulatory needs.

LFS will consider posting questions and answers regarding how LFS enforces regulations on our website so that stakeholders can see what questions are being asked and the answers being given. This will provide more clarity on enforcement, and also transparency, uniformity, and fairness, as LFS is the enforcement body and not the interpretive body.

He reported that a subcommittee on recruitment and retention was brought up at the last CLTAC meeting but there seemed to be little interest. He noted that the subcommittee did not need to be a large one and could benefit everyone as there is a general shortage of clinical laboratory personnel. He reported that

“LFS is requesting a motion to create a subcommittee to assist in recruitment and retention of staff by participating in brainstorming for unique ideas to bring people on board in state service by advising on compensation analysis, training opportunities, events to target that would likely have potential candidates for recruitment, and benefit entitlements.”

He also requested that a subcommittee be formed to assist with the response to the nine recommendations of the CSA audit report. He said the exact charge for this subcommittee can be formulated with Paul Kimsey, Ph.D., and the subcommittee.

He reported that the issue of guest speakers has been discussed in the past. For this meeting, Robert Hunter would be giving a report, but there had been interest in obtaining a speaker on digital pathology. He noted that as there had been some difficulty in obtaining speakers, and the department was looking into the possibility of reimbursing the travel expenses of guest speakers.

Ms. Becker noted that CLTAC meetings used to last the whole day but have become shorter, and due to time constraints, guest speakers will be invited as the agenda permitted. She noted that with the standardization of reports, the section reports could be made briefer, and important areas highlighted—this will help to abbreviate the agenda.

Mr. Thomas reported that Tina Kruthoff, Assistant Director of OSPHLD, who has a background in the area of statistics, helped to organize the statistics reports. Although not mandated, LFS is attempting to be more transparent with its activities and standardized reports should help with this effort.

He introduced Ellen Yasumura, Assistant Chief of LFS, who is in charge of the administrative section. She has a bachelor's degree from UCLA in East Asian Studies, a master's degree in social work from UC Berkeley, with an emphasis in organization,

planning, and administration, has experience as a private consultant, and has many years of government service as a field inspector, unit supervisor, analyst, and health program manager. She has been the Assistant Branch Chief of LFS since 2014.

He reported that the section chiefs report to her, and she to him. She reported that going forward, she will report on administrative issues such as recruitment and retention and staff updates; she has also been asked to be the Department liaison for the subcommittee on recruitment and retention. Mr. Thomas added that Dr. Kimsey will be the liaison for the CSA audit subcommittee, but he was unsure at the time who the liaison will be for the subcommittee on regulations.

Ms. Becker asked for more clarification on the subcommittees or what the processes would be for the subcommittees.

Mr. Thomas replied that there are many options, but that not all meetings need to be in person, and meeting schedules can be proposed by the liaison for the subcommittee to discuss. For the regulations subcommittee, questions for the subcommittee will be those that affect a greater part of the community; when those questions arise, meetings can be proposed by the liaison, discussed by the subcommittee for feedback, and official replies posted for the whole community so everyone will know how regulations will be enforced.

Ms. Becker asked regarding the timeframe from the start of a question to a response.

Mr. Thomas replied that it could be discussed, but he would like it to be within 60 days.

Dr. Nickel raised the issue of changing laws that create gray areas and that require new regulations, such as those in the personnel regulations package.

Mr. Thomas replied that this would be the second part of the process. He reported that laboratories have many people in positions to answer these questions, but if existing regulations are still unclear to them, those regulations need to be more formally addressed. He reported that the intent of the subcommittee is to have a mechanism to work with and report to the greater public regarding how LFS enforces regulations. If regulations exist that are unclear or are behind the times and require changes, laboratories want to know what to do in the meantime. He reported that the goal is to achieve clarity and consistency in requirements to assist in continuing to have good labs.

Dr. Hilborne reported that most laboratories just want to do the right thing, and while LFS says its role is to enforce and not interpret, enforcement is de facto interpretation as the enforcement depends on LFS' understanding. There has to be some level of interpretation, but whatever that understanding and enforcement is, it needs to be clear. Regarding the timeline, people want a fast turnaround, and the process should involve the CLTAC, but also the legal team, in order to get it right. He noted that perhaps the process of vetting the issues through the subcommittee could help to streamline the regulations writing process.

Mr. Thomas replied that policy must also be considered. With regards to inspections, they are not all inclusive, but are more like random audits, and outcomes differ from inspection to inspection. He reported that regarding meeting schedules, with more global issues, 60 days for a turnaround would be preferred due to the CLTAC's quarterly meeting schedule.

Dr. Hilborne moved that the CLTAC establish a committee on regulations that would meet by telephone once a month whenever any issues or questions are pending, and that the committee works out the process with LFS staff in terms of how the process would work.

Lori Dean-Yoakum asked if the motion could be changed to include scheduling flexibility.

Ms. Becker noted that the charge did not include specifics regarding the timeline or timeframes, so leaving those open for the subcommittee themselves to decide on would be fine.

Robert Hunter asked how questions and responses would be handled.

Mr. Thomas reported that the technical aspects are still being developed, but a group email will be set up, an internal LFS group will vet the questions, and selected questions will be given to the subcommittee for consideration.

Donna McCallum reiterated that complaints and investigations, including surveys and citations, will not be discussed.

Ms. Becker reported that there was a motion on the floor and asked if there was a second, Ms. Dean-Yoakum seconded.

Ms. Becker called for a vote. The motion carried.

Mr. Thomas asked the Chair provide the name of a Committee member to head each subcommittee within 30 days.

Ms. Becker asked about the process for forming a subcommittee and membership in the subcommittee.

Mr. Thomas replied that the bylaws do not specify, but in the past, the CLTAC Chair would suggest the name of a CLTAC member who would chair the subcommittee, and that person would recommend members for the subcommittee, who can also be interested public members.

Ms. Becker responded that she would put a note out to notify those members who were not present and anyone who was interested in facilitating the subcommittees could reply to her within the next 30 days.

Mr. Thomas noted that LFS will also name their liaisons in that time.

Ms. Pahland asked that for the regulations subcommittee, members be sought to represent all areas where there are current regulations packages.

Dr. Hilborne noted that there appeared to be two issues, one being regulation packages, and the other regarding responding to questions about existing regulations. Mr. Thomas replied that one subcommittee was recommended because the questions, being more global in nature, could lead to changes in regulations and additions to regulation packages. They agreed that the membership and ground rules for the subcommittee could be fluid to respond to future needs.

Ms. Becker asked Mr. Thomas to read the charge. Marjorie Braasch moved to set up the second subcommittee on recruitment and retention. Elizabeth Dequinia seconded.

Michael Aiden asked that should the motion pass, a member of the labor community be permitted to join the subcommittee.

Ms. Becker called for a vote. The motion carried.

Ms. Becker said that the subcommittee will assist with CSA audit and choose which among the nine items they would like to focus on.

Mr. Thomas replied the subcommittee can decide the specifics at a later time in conjunction with the Department liaison, Dr. Kimsey, but as mentioned, LFS would like to get feedback from the CLTAC regarding the audit.

Ms. Dean-Yoakum moved to set up the subcommittee to assist with the audit. Ms. Dequinia seconded.

Ms. Becker called for a vote. The motion carried.

Ms. Becker noted that a global email will be set up for each of the subcommittees. Dr. Kimsey noted that he would like to have feedback on the audit sooner than 30 days. Ms. Becker asked the CLTAC members to volunteer themselves so the subcommittee on the audit can be set up and feedback provided as requested.

Lesya Vorobets of the CDPH Office of Regulations reported that the June 2016 date for the personnel regulations package on the regulations tracking log is the target date for completion of the draft, not the date by which the regulations will be signed off on and completed. The draft will then go through internal review and be released for public comment. Bridget Jones added that it is a first draft plus and ISOR.

Ms. Vorobets explained that ISOR stands for the Initial Statement of Reasons. It is required by the APA whenever regular rule making is done, and it requires that the program explain why it is changing or implementing the regulations. The ISOR explains the proposed adoptions, amendments, or deletions in the regulations text; it has additional requirements, but essentially functions as an explanatory document for the changes to the regulations text.

Ellen Yasumura reported on personnel issues. Between Richmond and LA, there are 14 vacancies, ten in Richmond and four in LA, with six examiners between the two sites, three program technicians, and four analysts, all in various stages of advertisement and interviews, except for the branch chief, which will come soon.

She welcomed Elsa Eleco, who agreed to step up from Examiner II to serve as the new section chief for Onsite Licensing. She has been with the CLIA section for 15 years for onsite inspections, the training of new examiners, and enforcement. She has a BS in Medical Technology from the University of Santo Tomas in the Philippines, has 25 years of experience as a CLS and a technical service in private industry, with expertise in quality assurance and quality control. She will step into her new role effective December 7, 2015, and will have overall responsibility for in-state and out-of-state inspection, enforcement activities, and coordination of AO approval and performance, as well as supervision and administration of her section.

She reported three new employees in Richmond. Ronnisha Harris, who comes to LFS from Covered California in Sacramento, is a new program technician working in Facilities Licensing, Johnny Sanchez, who comes to LFS from the State Franchise Tax Board, is a program technician working in reception. Lorelie Marquez, who comes to us from the Department of Industrial Relations in Oakland, is an office technician working in the mail room, filing, and document control. Ms. Yasumura also reported that examiner Howard Manipis, who had been working as a retired annuitant, has decided to fully retire.

7. Legislation update

Jan Otey, Examiner II for Facilities Licensing Section B, gave a brief presentation prepared by Mary Wogec on the three bills from the 2015 legislative session signed by the Governor.

She reported that AB 258, which prohibits California transplant centers from disqualifying the recipient of an anatomical gift based solely upon a potential recipient's status as a qualified medical marijuana patient, or based solely upon a positive test for the use of medical marijuana by a potential recipient who is a qualified patient, except to the extent that the qualified patient's use of medical marijuana has been found by a physician and surgeon, following a case-by-case evaluation of the potential recipient, to be medically significant to the provision of the anatomical gift. AB 258 deals with eligibility requirements for organ recipients, was signed and will have no effect on statutes or regulations enforced by LFS. She noted that the organ transplant program is a federal program and the policy is up to individual transplant centers and hospitals. .

She reported that AB 599, which amends Section 1270 of the Business and Professions Code (BPC) to expand the scope of practice of licensed cytotechnologists, authorizes a licensed cytotechnologist to perform all tests and procedures pertaining to cytology, including microscopic and nonmicroscopic methodologies and tests and procedures that utilize molecular or genetic methodologies that are performed on cytologic specimens related to infectious disease or cancer diagnosis. The tests must be performed under the overall operation and administration of a laboratory director in a laboratory certified in the subspecialty of cytology. In response to the enactment of this law, LFS will amend

personnel licensing regulations in Title 17 of the California Code of Regulations (17 CCR 1060, 1061, 1062) to expand the scope of practice of cytotechnologists according to the provisions of the bill.

She reported that AB 940 amended five sections of the BPC. It deleted the requirement that a laboratory director substantially meet the laboratory director qualifications under CLIA. It amended the definition of laboratory director to require that one laboratory director shall meet the qualifications of the federal Clinical Laboratory Improvement Amendments (CLIA), and to allow a bioanalyst qualified under CLIA to serve as a laboratory director in addition to the CLIA-qualified director in a laboratory performing high complexity testing. It allowed an applicant for bioanalyst licensure to obtain the experience required for California licensure in an out-of-state laboratory certified under CLIA rather than a laboratory approved by the California Department of Public Health (CDPH). It authorized license renewal fees for clinical cytogeneticists and clinical molecular biologists and made other minor clarifications. LFS will revise personnel licensing regulations in 17 CCR according to the provisions of this bill and will revise its webpages and corresponding PERL pages for bioanalyst licensure to add new information.

Changes to the online application system

Tina Kruthoff reported that the front end of the online application system went live on September 28 and the back end went live two weeks after. As of November 1, LFS personnel licensing staff had processed 1,000 applications. The installation of the system has helped to improve the approval process greatly.

She encouraged everyone to look at the LFS website. As part of the PERL project, changes and updates were made to all the personnel webpages to make them more user friendly, up to date, and uniform. LFS will continue to improve the site, moving to the facilities pages next. She noted that when pages go down, it should only be for a few minutes.

She reported that the upcoming PERL II project would put personnel license renewals online. She noted that ITSD was making changes to the request for proposal (RFP); once it is approved, it will go out for bid and the chosen vendor will start work on renewals; LFS expects that to happen around the beginning of the year.

Replying to a question, she reported that renewal notices will continue to go out as usual in the mail after the online system goes live, and if applicants have an email on file, they will also receive an email notice.

Dr. Hilborne asked if a quarterly update on the turnaround time could be provided so comparisons could be made from before and after the online systems goes live.

Ms. Kruthoff replied that it was one of the reasons why LFS is producing statistical reports. The last report was from the first quarter and shows there was a slow-down in September around the time of implementation. She noted that LFS has also made deliberate attempts to clear the backlogs, especially with clinical laboratory directors. She thanked Desiri Moret-Blyden, the analyst who has been responsible for the format

of the statistics; she added that any suggestions on the format should go to Ms. Moret-Blyden.

Elizabeth Dequinia asked if a letter could be sent out regarding the new system so laboratories could post the notice.

Ms. Kruthoff replied that the Department had not planned to do that, but would discuss it internally to see if a notice letter would be necessary.

Mr. Thomas added that the system was envisioned to be transparent to the user when they registered. Replying to Dr. Hilborne, he said that the new system is more automated, which would help to reduce the workload on the staff as they do not have to write emails. And he asked Ms. Kruthoff to introduce the PERL team.

Ms. Kruthoff reported that Martha Obeso was the lead examiner who has been the subject matter expert working with ITSD on every aspect on the LFS side of PERL for the past 11 months. Another lead was Minda Imbong, who supervises the program technicians who process phlebotomy applications. Also working on the project were Nyla Dagget, a program technician II working with phlebotomy applicants, and Karen Demby, examiner I with facilities. She thanked them for the hundreds of hours they devoted to getting the system online.

Revised draft CLIA 2003

Rhonda Becker reported that there was a lengthy discussion on the crosswalk matrix during the last meeting; as requested, the CLTAC members provided (four) comments on what they would like to see to the Department within 30 days.

Kathy Williams noted that the Crosswalk had shrunk due to the trailer bill, SB 75, which adopted many parts. Originally, in the SB 113(Maddy, Chapter 510, Statutes of 1995), California incorporated only section H-proficiency testing, J-facilities, K-quality control, P-quality systems. With SB 75, the state incorporated the new Subpart K from CLIA 2003. This new Subpart K included standards from several of the other sections of CLIA 1994; by incorporating all of the CLIA 2003 quality systems in Subpart K, it automatically incorporated about 99 percent of the original crosswalk. There is no need to address the stringency requirements of that crosswalk with the exception of about 10 standards that were not absorbed in quality systems, which are in the new packet.

She reiterated that the original charge was to determine stringency; and that is the focus of the crosswalk sent out with the agenda.

She reported that on page one, in the final column of D3009, it stated that "CMS will not access" where it should read, "CMS will not assess."

Ms. Becker noted that on page one, D2016, in the far right column, the word "requirements" was misspelled. Dr. Hilborne added that "reference" was also misspelled.

Dr. Hilborne referenced the last column of D2016, which says, "Revised by changing 90% consensus requirement to 80% consensus of reference labs", and noted that the

chart was still not clear enough. He pointed out that while the Crosswalk referenced laws that are being changed or adopted, it did not spell those laws out in the chart itself. He noted that terms should be defined, referenced laws written out, the argument for the stringency recommendation stated, and the final outcome should be spelled out in the document itself. He noted that ultimately, the CLTAC would adopt the Crosswalk and adopt CLIA as there was little alternative, and no evidence of harm to public health, but that the reasons for the determinations could be better documented.

Ms. Becker moved to the next item on the Crosswalk, D3005, unidirectional workflow, being more stringent; the consensus was that it would be adopted. The third item, D3009, being more stringent, was straightforward and would be adopted.

On page two, it was noted that with current access to electronic documents, a safety board posting may be less practical, but federal law only requires that it be made "accessible," and so, is less stringent. D3013, regarding slides and blocks storage conditions, is more stringent.

Ms. Williams reported that for D3025, transfusion reactions, the AABB prevention techniques are scattered whereas the 2003 asked for a single, standalone procedure. Ronald Harkey, Section Chief, Facilities Licensing Section B, added that the quality systems standard covers it logically, but does not provide the information in a manner that would satisfy the requirement.

Mr. Harkey reported that it would be difficult to make the transition as most hospital were accredited but are not blood banks and do not have blood bank licenses, as they do not collect or produce. LFS is required to oversee transfusion services, but hospitals are not blood banks, and LFS emphasis is on licensed blood banks. LFS investigates transfusion reactions based on what happens in a clinical or hospital laboratory.

Jonathan Bautista noted that blood banks would follow AABB standards regardless.

Rhonda Becker reported that there was no opposition to D3025, so it would be adopted.

Rhonda Becker reported that D3027 was equivalent stringency.

Lori Dean-Yoakum noted that for some of the items covered by D3027 on records retention, the federal standard would be less stringent. Ms. Williams noted that the rating of equivalent stringency was an overall aggregate. She added that the more stringent requirement would always apply.

Karen Nickel noted that some provisions of CCR §1050 would apply to the current discussion. Ms. Pahland responded that while it was not yet decided that parts of CCR §1050 were going to be repealed, it was not being done in isolation, and they were coordinating efforts.

Dr. Hilborne alluded to the previous meeting, where there was a discussion on this item and the stringency recommendation, noting that while it may be correct that the group average may be equivalent stringency, it would be better if it were noted that some were more stringent, some less, and some equivalent.

Ms. Pahland asked if there was an item that is in fact less stringent as it would make a difference because once it was adopted and published in the register, it would be effective.

It was confirmed that Appendix A, provided for the previous meeting, delineated the items referenced in D3027, and there less stringent items.

Ms. Becker noted that D3041 should be a less stringent.

Dr. Hilborne asked again that the variance that pushed the particular determination and the specific portions of state and federal law where the conflict can be found should be noted in the chart. Ms. Becker asked that Appendix A also be referenced where applicable.

Ms. Becker asked Ms. Williams what was the difference in laws for D3045. Ms. Williams replied that it would be found in Appendix A with state law requiring retention for three years on some items as opposed to two years for the federal requirement.

Ms. Becker noted that D3045 should be less stringent.

Ms. Becker noted that there were a few typos to be fixed and updated with the recommended changes. Once the document was corrected and presented for review, a vote could then be taken by email, voting “yes” for agreement with the revised document and “no” for disagreement.

Report on Tissue banking and biologics

Robert Hunter reported the state had adopted the AABB standards and noted that many of their records retention policies were lengthy and were more stringent. He reiterated that it is not the hospital’s responsibility to advise patients regarding requirements of the Paul Gann Act—it is the physician’s responsibility.

He reported on a particular complaint that was a perfect storm that included problems with the lab, nursing, and emergency room component. One of the requirements for drawing blood for potential transfusion is that there is a patient identification system in place that meets all the requirements of AABB and that they are all verified in the presence of the patient. Currently, while no accrediting organization requires it, many hospitals have implemented a policy to require a second typing for those patients who may require a transfusion but do not have a blood type on file; he noted that not having a second tube from a different draw at a different time would render the policy moot.

Regarding the case under discussion, the patient had a classic hemolytic transfusion reaction. The nurses missed the signs and symptoms of transfusion reactions. He reiterated that nurses should carefully observe the patient for the first 15 minutes and listen to the patient and family members for complaints. He noted that hospitals were also inconsistent in their use of Fahrenheit or Celsius. Indicators were discovered in the lab testing, but were not reported, and it was unclear if the tube was mislabeled or drawn from the wrong patient; there was no separate armband, and no second check.

He reported that an email box has been created for an anonymous way for reporting concerns about a blood bank, biologics@cdph.ca.gov.

He reported that he has received many complaints about West Nile, unlicensed personnel working in immunohematology, and unlicensed personnel working in blood banks, transfusion centers or reference labs in a blood center. He asked that directors pay attention to how personnel were assigned.

He reported that there was a complaint about someone paying blood donors, and the complaint would be referred to CMS.

Tissue Bank and Biologics update

Ronald Harkey reported that Tissue Banking and Blood Banking complaints statistics will be included in future reports. Regarding applications, he cautioned that the blood bank license process is long, and it will take two to three quarters to be able to show approvals.

Facility Licensing Section Update, Richmond

Kathy Williams reported that every new business procedure being implemented in LFS is also being done by facility licensing. She asked the CLTAC if they would like a breakout of details for the reporting of complaints.

Dr. Hilborne replied that a summary was fine, but if there is something that would be useful to know, it should be included. Ms. Becker added that if there were spikes that would certainly be something they would want to know about.

Ms. Williams reported that there were spikes in draw station complaints, spikes in miscellaneous, quite a number about unauthorized persons testing.

Dr. Hilborne asked if the complaints were substantiated, what was the root cause, how can labs learn from these types of mistakes? Were the complaints about phlebotomists substantiated or clustered? Could it be just one phlebotomist causing the spike?

Ms. Becker stated that details should be provided and if something needs more explanation, we could explore the root causes.

Tammy Pahland noted that complaints are confidential, are not subject to public records requests, and the details would be very limited.

Dr. Hilborne replied that the details and specifics were not necessary; broadly, the learning issue would be helpful: complaints about the personality of a phlebotomist, or if it is a training issue?

Ms. Williams reported that a process was put in place a year ago to forward complaints about laboratories that belong to chains to the corporate quality assurance officer and following up to see how the complaint was handled.

Ms. Pahland noted that her concern with confidentiality was that it was mentioned that the location could be reported; if there was only one lab that did that kind of work in that area, there would be an identity concern.

Dr. Hilborne replied that the exact location need not be identified, but that there was a geographic cluster. He added that what was important was not a report of complaints, but how the complaints were resolved and how the resolution could be implemented by other labs.

Facilities Licensing Section Update, Los Angeles

Victoria Maxwell, Examiner II in LFS Facilities C, thanked Ms. Moret-Blyden for her work on the statistics report. She added that Catherine Tolentino, Examiner I, was progressing in her intensive training and was looking forward to the coming year.

Personnel Licensing Section Update

Martha Obeso, Examiner II, reported in place of the section chief, Zahwa Amad, Ph.D.

She reported that LFS recently approved a third national certifying organization for CLS generalists, American Medical Technology (AMT); it was reviewed by a committee of five LFS examiners. The look back date for AMT examinations is Jan 1, 2014; it does not go back four years. The other two other approved national examinations are the American Association of Bioanalysts (AAB) and the American Society for Clinical Pathology (ASCP). LFS also recently completed the review of a national certifying organization for phlebotomy and was in the process of notifying the organization of questions the Department had regarding scope of questions on their examination.

The Hospital Council (HLWI) met November 18, 2015, and asked about the CLS training programs. There were twelve CLS training program applications reviewed, and in the last six months, eight were approved and would be posted on the LFS website soon. The approved programs were one for histocompatibility in Mothra, one for chemistry in LA, two for CLS generalist in Ukiah and West Hills, and four for the genetic molecular program, one in San Diego, two in Carlsbad, and one in San Francisco.

LFS also conducted an oral exam for the licensing of directors on November 16, 2015; there were five candidates and four panelists. There were three genetic molecular biologists, one histocompatibility laboratory director, and one toxicologist.

She reported that another oral examination will be held on December 14, 2015, for five candidates (two for genetic molecular biology, one for cytogenetics, two for chemistry).

CLIA Update

Donna McCallum reported that CMS had previously sent out two letters to all non-waived labs, one on September 30, 2014, and one on January 20, 2015. The most current letter that announced the end of EQC on December 31, 2015, was supposed to have been sent out on November 30, 2015, which explained the concept of IQCP and that it must include the risk assessment quality control and quality assessment, and must include all five of the components: specimen, test system, reagent, environment, and testing personnel.

She reported that LFS has a memo regarding EQC and IQCP in California on its website, which also has links to the CMS site information.

She reported that interpretive guidelines were to be released by January 14, 2016, which would remove the EQC guidelines, and include the IQCP regulations. Surveyors will inspect as they normally do. There will only be two options, IQCP or the original CLIA regulations. In terms of IQCP, the surveyors will make sure that all three of the parts are present, and the five components that fall under risk assessment. Surveyors will still do the outcome oriented survey process; the only difference will be that if there is a deficiency, it will appear on the 2567 statement of deficiency and not in an educational letter. She noted that if a facility decides to use IQCP but doesn't include all the components or parts, it will be a citation.

She reported that the Clinical Laboratory Standards Institute (CLSI) document was removed from the last update of the interpretive guidelines, so many who used the CLSI document may go to IQCP because if they do not, they must go back to the default regulations.

She noted that all the surveyors across the nation attended an extensive webinar on applying this to the survey process, and those who passed received a certificate. They are prepared and the responsibility is on the laboratory director to approve the IQCP policy and ensure that all the parts are addressed.

Robert Footlik commended Tammy Pahland and Department for finding a legislative vehicle to amend BPC §1220, which paved the way to legalize EQC and IQCP in California. Ms. Pahland noted that she could not take credit and that it was a team effort.

Mr. Thomas added that EQC became an option in California on June 24, 2015 but went away on December 31, 2015, and IQCP became an option on January 1, 2016.

Robert Hunter asked that facilities check with their Accrediting Organization (AO) for acceptance of IQCP and they have their own formats that they will give to their labs. The last letter went out to labs and leaves it to the AOs to specify how they will implement and inspect, but their methodology will already have been approved by CMS.

Donna McCallum reported that all the AOs under CMS have presented their change in processes to accommodate IQCP and they will send their formats to their laboratories. The letter that went out on November 30, 2015, included certificates of compliance, as they were leave it to the AOs for guidelines on how they would implement and inspect as their methodology was already approved by CMS.

Recognition of Lorri Dean-Yoakum

On behalf of LFS, Robert Thomas thanked Lori Dean-Yoakum for her exemplary service to the CLTAC and the community. Ms. Dean-Yoakum has work experience in both hospitals and independent labs. She is a member of the California Clinical Laboratory Association (CCLA), which she served as president for two years, and is currently working in quality management. She started to attend CLTAC meetings in 2000, and

joined the CLTAC as a member in 2007, having been nominated by CCLA. In 2010, she was elected Chairperson.

Mr. Thomas presented Ms. Dean-Yoakum with a certificate of appreciation. He noted that her participation was always superb, she brought up many items for discussion that were always interesting and informative; and as chair, she did an excellent job of conducting meeting and was active in organizing and assisting with arranging the agenda. He added that he always found her to be helpful and insightful, especially when discussing matters concerning the CLTAC.

Ms. Dean-Yoakum thanked the Department, Mary Wogec for her minutes, Dennis Tavares for the setup in Richmond, Kaiser for their help with the Southern California arrangements, Karen Nickel for her mentorship, noting that she could not have done it without Robert Footlik. She thanked everyone for the opportunity to serve the CLTAC and for having confidence in her.

Election of Officers

Ms. Becker reported that every December, the composition of the CLTAC will be discussed. There are three members whose first term will end in December, while three others whose second term will end. She reported that a new chairperson will also need to be elected.

Ms. Dean-Yoakum nominated Rhonda Becker for another term as Chair. Dr. Hilborne moved that the nominations be closed; Ms. Dequinia seconded the motion.

Ms. Becker called for a vote. The motion carried.

Mr. Thomas reported that the first term of three members of the CLTAC will expire: Marjorie Braasch, nominated by Engineers and Scientists of California, Local 20; Margie Ann Morgan, nominated by the American Society for Microbiology; and Fred Ung, nominated by the California Coalition of Clinical Laboratory Professions. He noted that all three have been contacted along with their organizations; the organizations have nominated each to continue on the CLTAC and each has consented to continue for a second term.

He reported that the members whose second term was set to expire were: Anthony Butch, Ph.D., nominated by the American Association for Clinical Chemistry (AACC); Ms. Dean-Yoakum, nominated by CCLA; Elizabeth Dequinia, nominated by the Philippine Association for Medical Technologists (PAMET); and Laurie Fuller, nominated by the California Association of Cytotechnologists. The Department has already approved CCLA's nomination of William E. Gardner to fill Ms. Dean-Yoakum's position. LFS had received notification that California Association of Cytotechnologist nominated Matt Riding, PAMET nominated Danilo Dominguez, and Imre Fischer reported that AACC nominated Lu Song, Ph.D. Mr. Thomas thanked the associations for their nominations, noting that once their nominations and curricula vitae were received, the Department would work to get their nominations approved.

Everyone thanked the departing CLTAC members for their contributions and efforts during their years on the Committee.

New Business

Ms. Dean-Yoakum reported that an ongoing subject of discussion was agenda items; she suggested that the agenda have a “hot topics” section. If members noticed something in the field that would affect the entire regulated community, they could bring it to the attention of LFS, who would vet it for discussion at the CLTAC; LFS would investigate the issue and report back to the community.

She reported that she became aware of a couple of free-standing phlebotomy companies run by phlebotomists not attached to a clinical laboratory or laboratory director. Maybe the phlebotomists do not know they cannot do that. As a hot topic, the whole community could be reminded of what the regulations were regarding that and how to comply with the regulations. With the charge to create a subcommittee on regulations, the idea of hot topics for the agenda might not be needed.

Mr. Thomas reminded everyone that phlebotomists are covered by BCP §1246, that there are certain rules, including who can supervise phlebotomists.

Future Items

Rhonda Becker asked if there were suggestions for future business.

Next meeting

Rhonda Becker announced that the next meeting of the CLTAC would be held on Friday, March 4, 2016.

Adjournment

Dr. Hilborne motioned to adjourn and the motion was seconded by Ms. Dequinia, the CLTAC board voted to adjourn.